ASGCT NEWS | PRESIDENT'S MESSAGE

Approved mRNA Vaccine for COVID-19 is a Milestone for Gene and Cell Therapy

Stephen J. Russell, M.D., Ph.D. - December 11, 2020

ASGCT President Stephen J. Russell, M.D., Ph.D. reacts to today's FDA approval of the first COVID-19 vaccine authorized for use in the U.S.

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Today's **FDA approval of the COVID-19 vaccine** BNT162b2 from Pfizer and BioNTech marks a great day for the USA and a significant milestone for the field of gene and cell therapy.

Not only will this vaccine be a critical step in protecting people from a virus that has killed more than 1.5 million people and overwhelmed hospital systems worldwide. It is the first-ever mRNA vaccine or drug approved by the FDA, representing a culmination of decades of research that now demonstrates the safety and efficacy of gene therapy on the world's stage.

The vaccine uses mRNA to program a person's cells to produce many copies of a fragment of the SARS-CoV-2 virus. The fragment then educates the immune system to attack if the real virus tries to invade the body. It requires two doses, administered three weeks apart.

BNT162b2 has an efficacy rate of 95 percent and has already been approved for use in Britain, Bahrain, Canada, Saudi Arabia, and Mexico. A 95 percent efficacy means that for every 100 nonvaccinated people that get infected with the virus, only five vaccinated people will get infected

The development timeline of this vaccine—the first to generate late-stage data in the U.S.—**was historic**. BioNTech researchers began working on the vaccine's design in January. The company then partnered with Pfizer in March and launched a clinical trial in May. By the end of July, the companies announced they had launched a phase 2/3 trial including 30,000 volunteers in the U.S., Argentina, Brazil, and Germany.

Pfizer has said it will be able to supply up to 25 million doses before the end of the year, and 100 million total vaccines by March.

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